REMARKS

Claims 1, 7-10, 14-20, 26-32, 38-40, and are pending. Claims 1, 26-27, 31-32 and 38 have been amended.

The issues outstanding in this application are as follows:

- Claims 1, 7-10, 14-20, 26-32 and 38-40 have been rejected under 35 U.S.C. §112, first paragraph, as not enabled by the Specification.

- Claims 1, 7-10, 14-19, 26-32 and 38-40 have been rejected under 35 U.S.C. §103(a), as being unpatentable over Van Bree et al. (WO 01/72322).

I. 35 U.S.C. §112, first paragraph

Claims 1, 7-10, 14-20, 26-32 and 38-40 have been rejected under 35 U.S.C. §112, first paragraph, as not enabled by the Specification. Applicant has amended the claims. In view of these amendments, Applicants request that the rejection be withdrawn.

II. 35 U.S.C. §103(a)

Claims 1, 7-10, 14-19, 26-32 and 38-40 have been rejected under 35 U.S.C. §103(a), as being unpatentable over Van Bree et al. (WO 01/72322).

To establish a *prima facie* case for obviousness, all claim limitations must be found or suggested in the references cited or within the general knowledge in the art. Applicant has amended the claims. In view of these amendments, Applicants request that the rejection be withdrawn.

a. "wherein the N-terminal lactoferrin variant retains the same biological function as full length lactoferrin"

The Examiner cites the disclosure of N-terminal lactoferrin variants in Van Bree where the N-terminal amino acids 2-5, which form a basic amino acid cluster, are deleted or mutated to remove the positive charge(s). Office Action 04/24/06, pg 8. Van Bree is quite clear that these variants do not "retains the same biological function as full length lactoferrin." Pg. 16, lines 14-17. As is evidenced by Van Bree, this consequence of neutralizing the N-terminal basic cluster was well known in the art. The loss of Lipid A binding is not inconsequential to the pending method claims. *See* pending Specification, *e.g.*, at Examples 1-5 and 15-16. Thus, Van Bree does not disclose or suggest all limitations of the claims as amended.

b. Oral Administration

Van Bree teaches oral formulations of Lactoferrin. Pg. 26-27. However, Van Bree also teaches that the "particular form of the composition varies with the intended mode of administration and therapeutic application." There is no suggestion or teaching to use oral lactoferrin in the treatment of bacteremia. On the contrary, Van Bree teaches intravenous administration of lactoferrin at high dosages for Bacteremia. Pg. 3 and Examples; Pg. 22 lines 7-12. This intravenous administration is used to introduce Lactoferrin systemically to directly bind and thereby neutralize and accelerate clearance of LPS. *Id.* at pg. 3, lines 22-24. Taken as a whole, Van Bree cannot be fairly viewed as teaching or suggesting oral administration for bacteremia related sepsis. MPEP 2141.02 (VI.)

In view of the above, applicant believes the pending application is in condition for allowance.

Applicant believes no fee is due with this response. However, if a fee is due, please charge our Deposit Account No. 06-2375, under Order No. HO-P02703US2 from which the undersigned is authorized to draw.

Dated: September 26, 2006

Respectfully submitted,

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